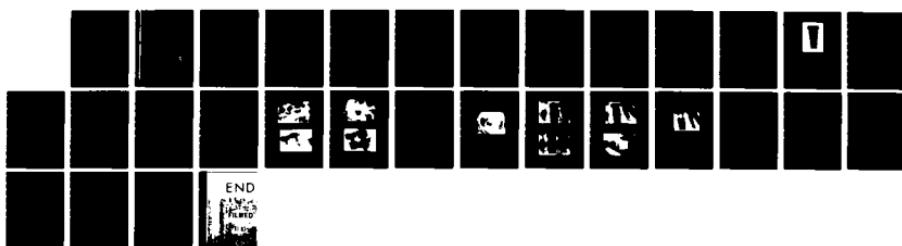


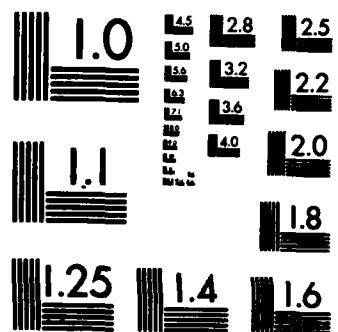
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REPORT NUMBER 10

SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

Annual Report

Craig R. Hassler, Robert H. Downes,
Gary L. Messing and Orville E. Russell

December 1979

Supported by

U. S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
Fort Detrick, Frederick, Maryland 21701

Contract No. DADA-17-69-C-9181

BATTELLE
Columbus Laboratories
505 King Avenue
Columbus, Ohio 43201

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ceramic. The upper two parts of the implant (post and core and crown) are conventional dental materials, usually gold. Roots are produced by grinding bisque fired alumina stock on a computer controlled milling machine. This technique provides high quality, high strength, and design flexibility. A series of nineteen graded sizes of implants have been produced. In the last year design modifications and improved fabrication techniques have allowed the production of roots small as 4 mm x 4 mm in cross section. Extensive quality assurance has been performed on the implants intended for human implant. Quality assurance procedures include: wet densities, visual inspection and mechanical testing of test bars. The quality of alumina root has consistently improved throughout this project.

Long term implants are being followed in the baboon colony. "Success" continues to be at the same level as reported in the previous year. The "success" rate for roots ingrown and in function has been 90%. As previously noted, failure of roots usually occurs during the initial 3-month ingrowth period. This ingrowth period is most crucial to the overall success of the implant. The three piece design as well as the wide variety of available sizes assists in minimizing loss during the ingrowth period. Presently, 28 roots (27 in function) are being followed in baboons. Time of success in function is over 4 years in some animals. The human implant study has been underway for eighteen months. To date, 25 patients have been implanted, four patients have been reconstructed. The clinical course appears similar to the baboon, except ingrowth appears to be considerably slower. Overall "potential success" rate in humans is 85 percent.

It is intended that the animals and patients in this study be followed as long as possible so that the true long-term effects of such an implant system can be adequately evaluated.

FOREWORD

This study has been conducted at Battelle's Columbus Laboratories utilizing the staff and resources of the Bioengineering/Health Sciences Section and the Ceramics Section. The clinical portion of this study has been conducted at The Ohio State University College of Dentistry.

This is the tenth annual report on progress under Contract No. DADA-17-69-C-9181, "Surgical Tooth Implants, Combat and Field". The principal investigator for this research was Dr. Craig R. Hassler, Ceramics research was directed by Dr. Gary L. Messing. The human studies have been under the direction of Dr. Robert H. Downes and have been conducted in the clinical facilities of the College of Dentistry. Clinical research was conducted under a protocol approved by The Ohio State University human subjects committee. Animal research, conducted at Battelle Columbus has followed the guidelines of the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and Use of Laboratory Animals of the Institute of Laboratory Animal Resources, National Research Council (DHEW Publication No. (NIH) 78-23, Revised 1978).

ABSTRACT

Long term implant studies of alumina tooth roots are being performed in both humans and baboons. The implants designed for this project are single root elliptical and rectangular designs with serrations arranged for maximal stress distribution of occlusal loads. The implant is of a three-piece design. The serrated root portion is alumina ceramic. The upper two parts of the implant (post and core and crown) are conventional dental materials, usually gold. Roots are produced by grinding bisque fired alumina stock on a computer controlled milling machine. This technique provides high quality, high strength, and design flexibility. A series of nineteen graded sizes of implants have been produced. In the last year design modifications and improved fabrication techniques have allowed the production of roots small as 4 mm x 4 mm in cross section. Extensive quality assurance has been performed on the implants intended for human implant. Quality assurance procedures include: wet densities, visual inspection and mechanical testing of test bars. The quality of alumina root has consistently improved throughout this project.

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SURGICAL TOOTH IMPLANTS, COMBAT AND FIELD

by

Craig R. Hassler, Robert H. Downes, Gary L. Messing
and Orville E. Russell

BACKGROUND

In the last several years a new generation of dental implants have evolved. These devices are designed to be rigidly affixed by bone ingrowth and provide minimization of stress usually by serrations⁽¹⁻⁴⁾ or pores.⁽⁵⁻⁶⁾ Generally, these implants are designed as single free-standing prostheses. Several biocompatible materials have been utilized including plastics,⁽⁷⁾ metallics⁽⁶⁾, and ceramics.^(1,2,3,8-17) Our laboratory has specialized using alumina ceramics incorporating a serrated design. In the past 10 years we have evolved a combination of material, design, and technique components which appear promising. It should be noted that all three components (design, material and technique) are of importance if an implant system is to be successful. Failure of any of the three can be detrimental. A serrated ceramic implant system based upon these principles is under test in our laboratories. Implant experience in animals exceeds 4 years of function. On the strength of the animal experiments, a clinical study was begun 18 months ago.

The lower portion of our three-piece implants are produced from alumina (Figure 1). This portion has large serrations into which bone ingrowth has been demonstrated.⁽⁴⁾ The upper two portions of the implant - post and core and crown - are cemented after ingrowth to allow function. The three-piece design allows minimization of occlusal stresses on the implant to facilitate bone ingrowth. An analogous situation is seen in the healing of long bone. It is assumed that as in long bone an orderly transition through a sequence of gradually stiffer bone materials proceeds (hematoma+ connective tissue+ woven bone+ compact bone). The maximal strain which any of these tissues can withstand must not be exceeded if healing is to proceed to completion.⁽²¹⁾ Consequently, strain upon the implant-bone

interface must be minimized early in the healing process if bone formation is to occur. Once the implant is stabilized by ingrowth, the large implant surface area at right angles to the principal load axis of the implant is intended to maintain bone stresses below a level which produce resorption of bone. Attempts to quantify these stresses have been made in this laboratory.⁽⁹⁾ This information is not specifically for alveolar bone. However, it serves as a guide in an area where no direct information is available. As demonstrated by data, the hypothesis appears to be viable and bone can exist successfully in direct contact with a functional implant.

The above mentioned parameters, unique to this design, are the serrations and three piece construction. They are the two major determinants for design success. A secondary design parameter which has proven useful is the use of a graded series of implants. This gradation allows optimal fit into the available site. Nineteen sizes have been produced for the clinical studies. Initially, both rectangular and elliptical implants were used in baboons. However, the rectangular shape appears to provide a better initial fit into fresh extraction site in pre-molar and molar regions. Consequently, this design is being used exclusively in clinical trials. The method of producing roots by contour grinding on a computer controlled milling machine has allowed for flexibility not only in size but in other design changes. In a research protocol, this ease of flexibility has been an asset and will continue to be our method of root manufacture.

The concept of providing adequate stress distribution area cannot be overemphasized. It appears to be fundamental to the apparent success of this implant. At this time, the long term animal success is encouraging. Success for a similar or longer time span in humans is necessary to determine the true success of the implant.

METHODSFabrication of Tooth Roots

Tooth roots were fabricated by essentially the same process as used in previous years.^(2,9) The rectangular design (Figure 1) as previously chosen for the clinical study was produced in smaller sizes than previously available.

The various sizes of implants prepared to date are given in Table 1. With the slightly modified root design it was determined that roots as small as 4 mm x 4 mm could be made with a 15 mm serration length. Root taper and serration depth were altered to provide necessary section thicknesses. These modifications reduced stress distribution area by only 16 percent. Thirty-six roots with the design modification were fabricated. Implants with extended posts were fabricated as model stabilization anchors for avulsive trauma cases. The non-serrated upper portion was extended to a length of 7 mm in these implants.

Quality Assurance

Quality assurance procedures were performed on all tooth root after final sintering. These procedures included: wet densities, visual inspection and mechanical testing of test bars sintered with the tooth roots.

- (1) Density - The density of every tooth root was determined by a simple water immersion technique. To enhance the wetting of the surface, a surfactant was added to the water. The average density for all of the tooth roots was 97 percent of theoretical.
- (2) Visual observation - Each root was observed through a stereomicroscope to check for surface flaws.
- (3) Strength - The flexure strength of the sintered alumina was determined in 4-point bending with a specially designed testing jig.⁽¹⁹⁾ In most cases the tentative ASTM strength requirements of 58 Kpsi were exceeded. In ten of the roots, a flexural strength of only 54 Kpsi was observed. It is not clear at this time why the mechanical strength of this particular 'etc' was lower than previous batches.

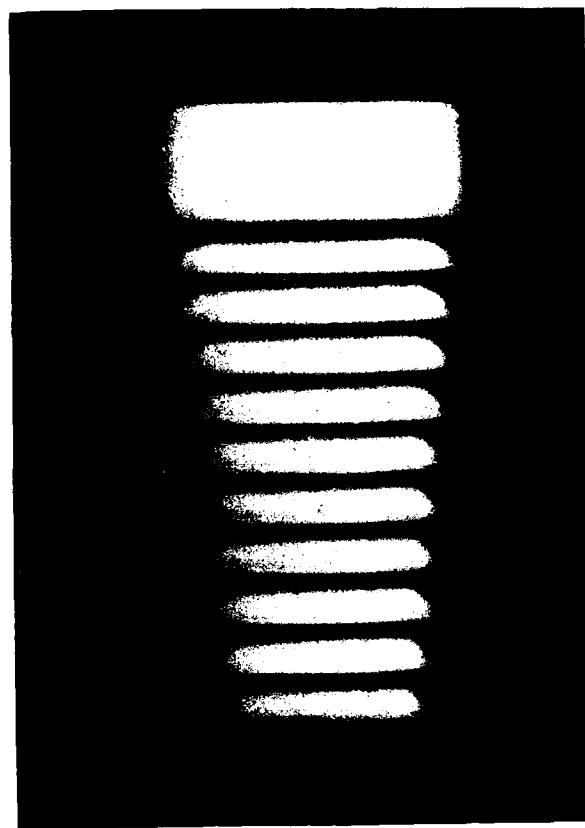


FIGURE 1. FINISHED ALUMINA ROOT PRIOR TO SURGICAL IMPLANT. THIS IS THE CERAMIC PORTION (PART 1) OF THE 3 PART IMPLANT SYSTEM. THE SERRATIONS ARE DESIGNED TO PROVIDE A LARGE SURFACE AREA FOR STRESS DISTRIBUTION OF OCCLUSIVE LOAD TO THE INGROWN BONE. THE HUMAN ROOTS ARE RECTANGULAR IN CROSS SECTION. THE POST AND CORE (PART 2) IS CEMENTED INTO AN INTERNAL RECESS IN THE ALUMINA ROOT (PART 1) AFTER INGROWTH HAS STABILIZED THE ROOT. THEN A CLINICAL CROWN (PART 3) IS FABRICATED USING STANDARD IMPRESSION TECHNIQUES.

TABLE 1. TOOTH ROOT SIZES (Millimeters)

Size	Size	Size	Size
4 x 4 x 15	8 x 6 x 15	9 x 9 x 15	10 x 10 x 15
4 x 5 x 15	8 x 7 x 15	10 x 7 x 15	11 x 8 x 15
5 x 5 x 15	8 x 8 x 15	10 x 8 x 15	11 x 9 x 15
6 x 5 x 15	9 x 7 x 15	10 x 9 x 15	11 x 10 x 15
7 x 5 x 15	9 x 8 x 15		
7 x 6 x 15			

This deviation points out the need for continued quality assurance to guarantee continued high quality of the finished product.

Baboon Implant Procedures

Animal implant procedures have been performed in the adult female baboon. Following extraction, the mandibular tooth socket, either molar or pre-molar, is shaped using a bone burr. A socket is formed by a continual fitting procedure. The root is firmly tapped into the alveolar bone until the uppermost serration is into bone. The roots are given no further attention, except administration of prophylactic antibiotics immediately post surgery and a soft diet for two weeks. The roots are observed periodically for three months. Radiographic examination and manual palpation indicate if the root is adequately stable for reconstruction. A similar procedure has been used to implant roots in edentulous sites.

Restoration of the implants is facilitated by prefabrication of a gold post and core prior to implantation. Following adequate stabilization by bone ingrowth into the serrations, the post and core is cemented into place. Impressions are taken. A gold crown is fabricated and cemented into place. Care is taken to provide correct occlusion. The implant is periodically examined and documented by radiographs and photographs.

Human Implant Procedures

Rectangular implants are placed in edentulous or fresh extraction sites in mandibular molar or premolar sites. Roots are placed in sites where they will function as single free standing implants when reconstructed. The roots are observed visually and radiographically through the study. As with the animal studies, a gold post and core was prefabricated for each implant. The patients are observed periodically until the implant is rigid or exhibits minimal motion. At that time the post and core is cemented, and a clinical crown fashioned. Periodic examination of the patient continues following reconstruction. All clinical studies are performed at The Ohio State University College of Dentistry in compliance with a protocol approved by the University human subjects committee.

RESULTSAnimal Studies

During the last year, long term observation of implants has continued in nine baboons. Again, as was observed last year, the failure rate has been low. Presently 31 roots are being followed in the baboons. Twenty seven of these roots have been reconstructed and are now "successfully" in function. In the last 4 years, 2 roots have fractured after reconstruction. One failure was after 3 months of function and the second after 23 months of function. The cause of the fracture is not known. However, these particular roots were produced from lower strength alumina than that presently being used. The apical portion of these roots are still firmly anchored in alveolar bone. A third failed root placed into function too soon (after 2 months) remains mobile after 33 months. This root is being followed to assess the fate of mobile implants. Crown height was reduced on this root to decrease its function. The root has not become inflamed nor is it mobile enough to allow easy removal. Bone ingrowth has been sufficient to provide retention. Apparently, mobility has promoted the generation of connective tissue. There does not appear to be a continued loss of alveolar bone.

Roots in function are considered "successful" by the following criteria:

- (1) Radiographic appearance of dense bone ingrowth into serrations
- (2) Resistance to movement by manual palpation (rigid)
- (3) Minimal gingival irritation
- (4) Maintenance of occlusion

Roots which have remained rigid but have not been put into function are termed "potentially successful" until they are reconstructed. All "successful" roots in this study were implanted a minimum of 3 months before reconstruction.

In the 9 animals still being observed, the following history of functional success has been observed to date:

<u>Number of Roots</u>	<u>Time in function (months)</u>
2	49 months
2	43 months
1	28 months
6	24 months
10	20 months
1	18 months
5	3 months
Total	27

When the three failed implants are considered, a total of 30 functional roots are now under study. The functional implant failure rate to date is 3/30 or 10 percent. When the implant history for the nine baboons in the colony is traced back to the beginning, an overall failure rate of 8/36 or 20 percent is observed. As previously noted, most of the failures occurred immediately following implantation. Failure rate has remained low compared to our earlier studies where failure rates during the first three months were 40 percent. Factors responsible for one dramatically decreased failure rate appear to be (1) a greater selection of root sizes available to assure better initial fit - both rectangular and elliptical roots were available; (2) longer roots now available; and (3) design changes to allow greater flexibility of vertical placement.

In the 9 animals now being observed, the total post implant time for roots is:

<u>Number of Roots</u>	<u>Time since implant (including nonfunctional time prior to reconstruction)</u>
4	50 or more months
10	30 " " "
10	27 " " "
4	18 " " "

Gingival irritation, however minimal, is a drawback of this implant in the baboon. The minor irritation appears to be related both to the approximation of gold to the gingival tissue as well as to the relatively poor oral hygiene of the baboon. Infection has never been a causative factor in the loss of an implant. Apparently, the environment in

the oral cavity allows the implant to survive even though there is no attachment of gingiva to the ceramic root. Fortunately, the mild gingival irritation present in baboons is not seen in humans. Histologically, gingiva is observed invading the upper most serration. In the majority of these implants, attachment of gingiva to the surrounding alveolar bone has been maintained.

Figure 2 shows two implants in function for 48 months. These implants are still successful by the indicated criteria. The band of gingival tissue is seen in multiple implants, most probably caused by some loss of bone gingiva attachment. Figure 3 shows a radiograph of the same implants as shown in Figure 2. Ingrowth of bone and the maintenance of that bone is apparent. There has been some vertical loss of bone. The loss occurred early in the implant history. Bone height has been stable for 2 years.

Figure 4 is another example of implants in long term function (3.5 years). Figure 5 is a radiograph of the implants in Figure 4. These particular implants also exhibit some vertical bone height loss and increase in bone density.

Clinical Chemistry and Hematology Results in Baboons

Throughout the project history hematology and clinical chemistry data have been collected on all animals at approximately 3 month intervals. The data for all animals has been compared to control (pre-implant) data. To date no value has shown a significant alteration from baseline. The parameters measured are: Glucose, BUN, Chloride, Bilirubin, Alk. phos., SGOT, SGPT, Creatinine, Na, Ca, Mg, K, Hemoglobin, Hematocrit, WBC, RBC, MCV, BANDS, SEGS, EOS, BASO, Lymph, Mono, Platelets, Retic and Pro-time.

Clinical Studies

To date, implants have been placed in molar mandibular sites in 25 patients. The patients have been followed periodically at increasing time intervals. As anticipated, the clinical course appears to be



FIGURE 2. BABOON IMPLANTS IN FUNCTION FOR 48 MONTHS
THICKENING OF THE GINGIVAL TISSUE IS SEEN
IN SOME BABOON IMPLANTS ESPECIALLY WHEN
IMPLANTS ARE PLACED IN ADJACENT SITES.

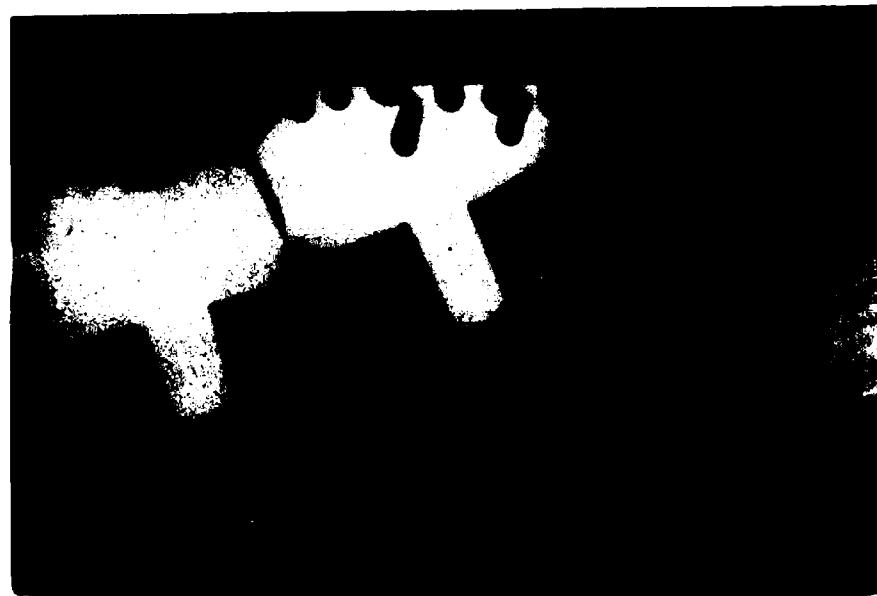


FIGURE 3. RADIOGRAPH OF BABOON IMPLANTS IN FIGURE 2. THIS RADIOGRAPH
TAKEN 3 MONTHS EARLIER THAN FIGURE 2 ILLUSTRATES THE TYPI-
CALLY DENSE BONE SEEN AROUND ANKYLOSED IMPLANTS. NOTE THE
LOSS OF VERTICAL BONE HEIGHT (APPROXIMATELY 1.5 mm). THE
ALVEOLAR HEIGHT HAS BEEN STABLE FOR THE LAST 2 YEARS.
THESE ROOTS ARE SHORTER THAN THE 15 mm ROOTS NOW USED IN
HUMANS.



FIGURE 4. IMPLANTS IN FUNCTION FOR 3.5 YEARS

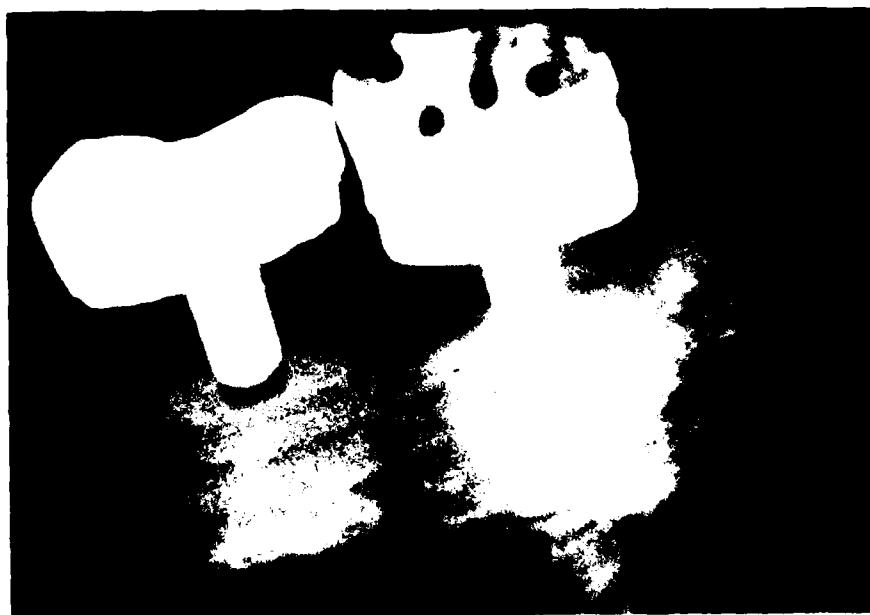


FIGURE 5. RADIOGRAPH OF BABOON IMPLANTS IN FUNCTION FOR 3.5 YEARS. AS IN THE PREVIOUS EXAMPLE, THERE IS A MARKED INCREASE IN BONE DENSITY ABOUT THE IMPLANT AND SOME LOSS IN VERTICAL BONE HEIGHT.

somewhat like the baboon; however, bone ingrowth is slower. The roots appear rigid for the first month following implant. They then loosen slightly, as exhibited by manual palpation. Radiographically, more bone loss is seen at the human alveolar crest than is evident in baboons. In the second and third month increased density of bone about the implant can be noted. The stability of the root increases at the same time. The average time until rigidization is 9 months. This is considerably longer than the 3 month period for ankylosis observed in baboons. This prolonged rigidization might be partially attributed to the difference in bone metabolic rate between baboons and humans. Additionally, our conservative approach in this first group of patients extended time until reconstruction. Our experience in baboons dictated that total ankylosis was necessary if the subsequent reconstruction is to succeed. Since relatively little was to be lost by waiting, we have often delayed reconstruction. On the other hand, a cooperative patient, as compared to the uncooperative baboon, might allow for successful early reconstructions and considerably reduce the waiting time required till reconstruction.

Gingival health (at the implant site) in all patients has been exceptionally good. No inflammation or suppuration has been noted. Post surgical pain perceived by the patients has been remarkably low in all cases. To date patients have remained pain free.

Post implant history of "potentially successful" roots is as follows:

<u>Number of Roots</u>	<u>Post Surgery Duration</u>
4	14 or more months
3	12 " " "
7	9 " " "
7	6 " " "
2	4.5 " " "
<u>23 total</u>	

Of these 23 potential successes, 22 are available for long term follow up. A total of 27 roots were implanted into 25 patients. Three of the patients exhibited an early loss of the implant, usually within 1 week. These roots extruded rapidly. Two of the patients elected to have a root replaced in the same area. Both of these patients are now potential successes.



FIGURE 6. HUMAN IMPLANT PRIOR TO RECONSTRUCTION

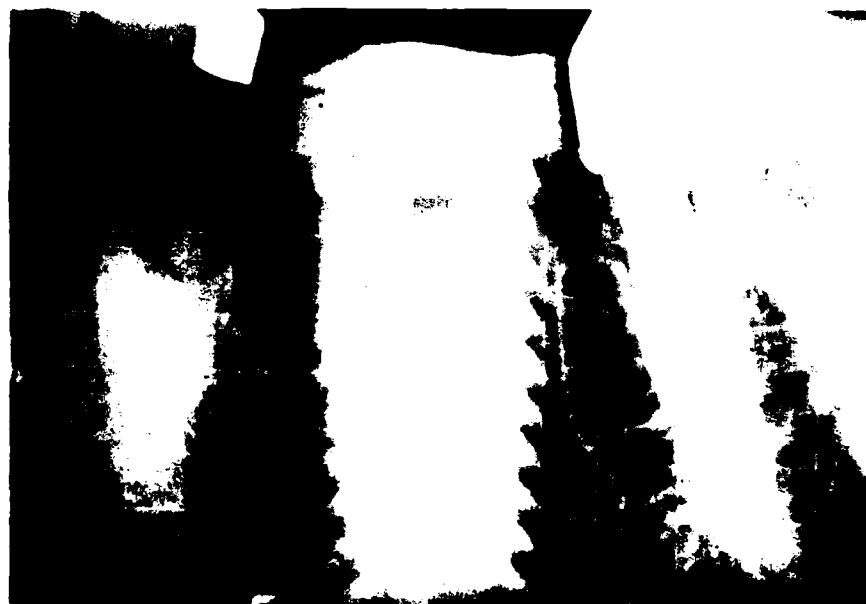


FIGURE 7. RADIOGRAPH OF IMPLANT POST SURGERY
(Figures 7-11 are all from the
same patient)



FIGURE 8. RADIOGRAPH OF IMPLANT 2 MONTHS POST SURGERY

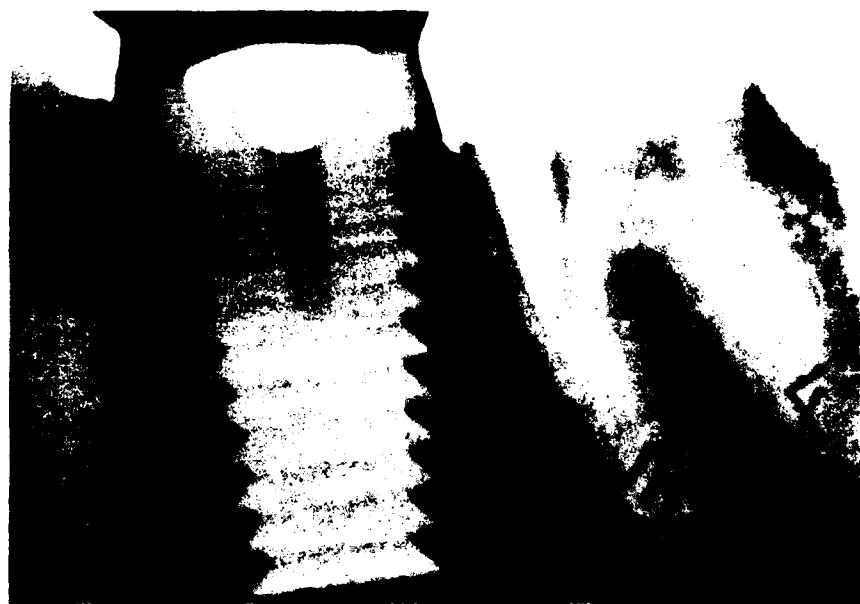


FIGURE 9. RADIOGRAPH OF IMPLANT AFTER 8 MONTHS POST SURGERY



FIGURE 10. HUMAN IMPLANT IN FUNCTION FOR 6 MONTHS
16 MONTHS POST SURGERY



**FIGURE 11. RADIOGRAPH 6 MONTHS OF FUNCTION
(Same time as Figure 10)**

Figure 6 shows a human implant prior to reconstruction. Gingival health surrounding the implant appears excellent. Figure 7 is the radiograph of an implant shortly after surgery. Note the areas void of bone both mesial and distal to the implant. Figure 8 is a radiograph of the same implant 2 months post-implant. Note the crestal bone height has been lost. Some loss is seen in nearly all patients. However, an increase in bone density around the implant is apparent. Figure 9 is the radiograph of the same implant 8 months after surgery. The radiodensity of the bone surrounding the implant has again increased, and vertical bone loss appears to have stabilized. The implant was reconstructed at this time. Figure 10 is the same implant 16 months after placement and 6 months in function. Figure 11 is a radiograph of the implant in Figure 9. This particular implant exhibited very slight mobility at the time of reconstruction, however the implant became ankylosed shortly after being placed in function. This is quite different than our baboon experience and probably reflects the cooperative nature of the patient.

At this time, 4 patients are reconstructed and using their implants without complication. Half of the implants were ankylosed at the time of reconstruction; the others exhibited slight mobility (approximately 1/4 mm buccal-lingual mobility). The clinical course appears to be that the slightly mobile roots rigidize after being put in function.

The roots implanted to date have been primarily in the mandibular first molar position. Also, two roots each have been placed in both the 2nd molar mandibular and 2nd bicuspid mandibular position. Both fresh and edentulous sites have been used. The most common size of implant used was the 7 x 6 x 15 mm root. The sizes of 9 x 7, 8 x 8, 8 x 6, and 6 x 6 were used occasionally. The availability of a wide range of sizes allowed for a snug fit within any available cavity. The size range was especially helpful in fresh extraction sites. In any case, proper size selection allowed for maintenance of gingival attachment to the surrounding alveolar bone. Maintenance of this attachment is crucial since there is no attachment to the implant. In six of the patients, some buccal migration of the

root, was noted during ingrowth. This indicates that some type of mechanical restraint would be desirable in patients if any migration is noted during ingrowth.

CONCLUSIONS AND RECOMMENDATIONS

The research progress to date continues to indicate a high probability of success for the serrated 3-piece tooth root designed in our laboratory. The failure rates continue low as periods of function pass the 4 year point in baboons. Success still appears dependant upon the initial ingrowth period during which the bone closely approximates the implant and rigidly fixes the implant in alveolar bone. The 3-piece design appears to facilitate the rigidizing process by providing an environment of minimal stress around the root in which hard tissue formation is favored.

Once bone has formed in the serrations, the serrations appears to provide adequate stress distribution so that normal occlusal stresses do not produce resorption of bone. Minimal gingival irritation is seen in baboons. This drawback has not led to the loss of any implant to date. The poor gingival health and/or the approximation of gold to the gingival tissue are probable causes of this irritation.

The clinical experience with this implant is still limited. The 25 patients in the study to date indicate that the success should be equal to that seen in animals. Unlike animals, gingival health is extremely good in humans.

One drawback of the implant in humans is the long ingrowth time until ankylosis. Fortunately, experience to date indicates that total ankylosis may not be necessary before reconstruction in humans. All patients reconstructed to date indicate total satisfaction with the implant.

The method of computer grinding implants from bisque-fired alumina continues to be a flexible and practical method of producing these implants. This particular machining sequence provides a very high strength and

quality implant. Bending tests, as well as visual and radiographic examination of fired alumina specimens and roots have been utilized to provide quality control for the roots.

The long-term animal implants should be continued for as long as it is practical. The valuable data being collected from these animals will probably never be available from a human study. The animal colony provides a captive, relatively uniform population which can be examined at will. Additionally, the animal population will provide histology samples and pathology data. Other implant sites are potentially available in these animals to investigate further design modifications. The human implant study should be continued to provide the ultimate answer as to the success of the implant. The method of root production presently being utilized is desirable for research purposes and should be continued. Major emphasis in root production should be placed on assuring high quality implants for experimentation.

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